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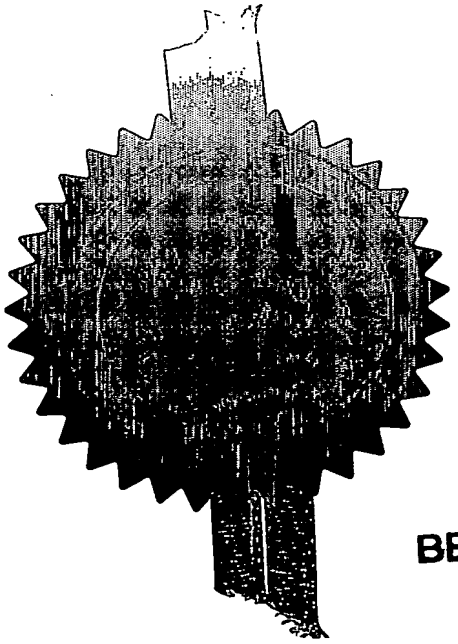

Signed

Dated 15 October 2004

Patents Form 1/77

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P01/7700 0.00-0323158.6

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office
Cardiff Road
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South Wales
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1. Your reference — MI04H11/P-GB

2. Patent application number *(The Patent Office will fill this part in)* — 0323158.6 — 3 OCT 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

MICROSULIS LTD
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ENGLAND

Patents ADP number *(if you know it)* 6936427003

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention — TREATMENT OF HOLLOW ANATOMICAL STRUCTURES

5. Name of your agent *(if you have one)*

HAMMONDS
RUTLAND HOUSE
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"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Patents ADP number *(if you know it)* 8622680001

6. Priority: Complete this section if you are declaring priority from one or more earlier patent applications, filed in the last 12 months.

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. Divisionals, etc: Complete this section only if this application is a divisional application or resulted from an entitlement dispute *(see note f)*

Number of earlier UK application	Date of filing *(day / month / year)*

8. Is a Patents Form 7/77 (Statement of inventorship and of right to grant of a patent) required in support of this request? — YES

Answer YES if:
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
Otherwise answer NO (See note d)

Patents Form 1/77

9. Accompanying documents: A patent application must include a description of the invention. Not counting duplicates, please enter the number of pages of each item accompanying this form:

Continuation sheets of this form	
Description	13
Claim(s)	4
Abstract	1
Drawing(s)	8

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent (Patents Form 7/77)	
Request for a preliminary examination and search (Patents Form 9/77)	
Request for a substantive examination (Patents Form 10/77)	
Any other documents (please specify)	

11. I/We request the grant of a patent on the basis of this application.

Signature(s) Hammonds Date 3.10.03

12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom JONATHAN MOORE 0870 839 3627

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Notes

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d) If you have answered YES in part 8, a Patents Form 7/77 will need to be filed.

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f) Part 7 should only be completed when a divisional application is being made under section 15(4), or when an application is being made under section 8(3), 12(6) or 37(4) following an entitlement dispute. By completing part 7 you are requesting that this application takes the same filing date as an earlier UK application. If you want the new application to have the same priority date(s) as the earlier UK application, you should also complete part 6 with the priority details.

Treatment of hollow anatomical structures

The present invention relates to techniques involved in the thermal ablative therapeutic treatment of the human body, and more particularly to treatment of hollow anatomical structures, for example varicose veins.

Most proposed treatments for varicose veins can be divided into the categories of schlerosing, mechanical manipulation, incision and removal of vein sections, and ligation. There are numerous examples of these in the art, and there are drawbacks associated with each.

Published European patent application EP-A-1,103,228 discloses a technique for treating vein defects in which a probe connected to a source of high frequency energy is introduced into a vein.

Thermal ablative therapies may be defined as techniques that intentionally decrease body tissue temperature (hypothermia) or intentionally increase body tissue temperature (hyperthermia) to temperatures required for cytotoxic effect, or other therapeutic temperatures required for a particular treatment.

The invention is concerned with hyperthermic thermal ablative therapies. Examples of these include RF, Laser, Focussed (or Ultra-High Speed) Ultrasound, and microwave treatments.

Microwave thermal ablation relies on the fact that microwaves form part of the electromagnetic spectrum causing heating due to interaction between water molecules and the microwave radiation, the heat being used as the cytotoxic mechanism. Treatment involves the introduction of an applicator into the tumours. Microwaves are released from the applicator forming a field around its tip. Direct heating of the water molecules in particular occurs in the radiated microwave field produced around the applicator rather than by conduction from the probe itself. Heating is therefore not reliant on conduction through tissues and cytotoxic temperature levels are reached rapidly.

WO99/56642 discloses a microwave applicator for applying electromagnetic radiation at microwave frequency comprising a coaxial input for a microwave signal input, a waveguide for receiving and propagating the microwave signal input, dielectric material positioned within the waveguide and extending beyond the waveguide to form an antenna for radiating microwave energy, wherein the coaxial input has direct in-line transition to the dielectric-filled waveguide. This direct in-line transition may be achieved by the central conductor of the coaxial input extending axially centrally into the waveguide so as to excite microwaves in the waveguide. A lateral conductor extends radially from the central conductor to assist the launch of the microwaves into the waveguide. The applicator may include a temperature sensor that is directly connected to the coaxial input. Another design of radiation applicator is disclosed in WO00/49957.

WO9956643 discloses a method of positioning on a microwave waveguide a sensor including an elongate metallic element comprising: selecting a tubular waveguide; determining the general orientation of the magnetic field generated during microwave transmission; and positioning the elongate metallic element substantially parallel to the orientation of the magnetic field. Connections of the sensor extend longitudinally of the waveguide and are connected to the outer wall of the waveguide and the central conductor of the coaxial cable that powers the waveguide.

There remains a need for techniques for varicose vein treatment that are effective, minimally invasive, avoid unnecessary surgery, and that are safe and easily controllable by the medical professional.

The present invention provides a method of treating hollow anatomical structures, for example varicose veins, comprising: providing an elongate member, the elongate member including an emitter, the emitter being coupled to a source of microwave radiation and being adapted to emit said radiation; introducing the elongate member into a hollow anatomical structure, the hollow anatomical structure including a section of target tissue; traversing the elongate member past the section of target tissue at a controlled rate while said emitter emits microwave radiation of a predetermined intensity into said section.

The hollow anatomical structure may be a vein, said section of target tissue comprising a section of varicose tissue.

Preferably, the traversing is performed at a predetermined constant rate. Preferably, said predetermined constant rate is about 2.5mm/sec.

Preferably, the elongate member is mounted on the end of a flexible elongate meter said elongate meter having a series of regularly spaced markings along its length; and said traversing is performed while a series of equally time-spaced audible tones is emitted; and said traversing is performed by a user at a rate such that each of said markings become visible to the user in time with a respective one of said audible tones. The traversing step may be performed by withdrawing the elongate member from the vein by the user pulling on the elongate meter, thereby exposing said markings.

The method may further comprise: providing a motion sensor, for example an optical sensor, positioned to sense the motion of the meter, and providing a controller, for example a computer, coupled to the motion sensor, wherein said traversing step is performed by withdrawing the elongate member from the vein by pulling on the elongate meter, wherein during said pulling step the controller issues audible and/or visible indications to the user, and wherein said audible and/or visible indications indicate that the speed of withdrawal of the elongate member is too slow, or is too fast, or is correct.

The method may include: providing a mechanical actuator, the mechanical actuator being coupled to the controller and adapted to impart translational motion to the elongate meter; wherein said pulling is

provided by driving the mechanical actuator, under the control of the controller and/or the user, to impart said translational motion and thereby withdraw said elongate member.

The method may include: providing a drum; wherein said step of pulling on the elongate meter includes winding the elongate meter onto said drum.

Preferably, the traversing step is preceded by the step of moving the elongate member in a first direction along the vein until the emitter has passed beyond said section of target tissue, and the traversing step is performed by the user withdrawing the elongate member in a second direction, opposite to said first direction.

In an alternative embodiment, the markings are non-regularly spaced, the audible tones are non-equally time spaced, or both.

Preferably, the markings comprise alternately light and dark coloured sections. Preferably, the light and dark coloured sections are each about 1 cm long. However, in alternative embodiments the markings may have any suitable dimensions corresponding to an appropriate sequence of audible tones in order to ensure a pre-determined withdrawal rate. The length of markings needs to be short enough to accurately guide the user, but not so short that the gap between the markings is unclear. Preferably, the elongate member is coupled to the source of radiation via a coaxial cable, and the markings are provided on the exterior surface of the coaxial cable.

Preferably, said predetermined intensity of microwave radiation is about 1.3 to 1.4 W per mm of circumference of the radiating portion of the elongate member, whereby said emission of radiation achieves occlusion of said section of target tissue during said traversing step.

Preferably, a temperature sensor is provided on said elongate member, and the method further includes monitoring a temperature provided by the sensor and indicative of the temperature of the section of varicose tissue during said traversing step. The method preferably further includes stopping the emission of said microwave radiation if the temperature sensed by said sensor is at or above a predetermined level.

According to another aspect of the invention there is provided an applicator for applying radiation to hollow anatomical structures, for example varicose veins, comprising: an elongate member, the elongate member including an emitter, the emitter being coupled to a source of microwave radiation and being adapted to emit said radiation; wherein the emitter includes a radiation emitting portion made of dielectric material and having an axis of elongation, and an elongate conductor within and extending at least partially along the radiation emitting portion, the radiation emitting portion being shaped and dimensioned so as to emit said radiation at a predetermined intensity in a field of limited dimensions adjacent thereto, whereby occlusion of the tissue of a hollow anatomical structure within said field is effectively accomplished.

Preferably, the radiation-emitting portion includes a generally conical tapering portion, the tapering portion thereby forming a tip for insertion into a hollow anatomical structure.

In one embodiment, the elongate conductor extends along the entire length of the radiation-emitting portion, whereby said field is disposed, in use, substantially around said tip.

In another embodiment, the elongate conductor extends partially along the length of the radiation emitting portion, whereby said field is disposed, in use, substantially around the midsection of said radiation emitting portion and spaced apart from said tip.

Preferably, a temperature sensor is provided on said elongate member, said temperature sensor preferably comprising a thermocouple, a fibre optic sensor or a thermistor. Preferably, the elongate member is coupled to the source of radiation via a coaxial cable, and a portion of said cable in abutment with the radiation emitting portion is surrounded by, and attached thereto, by a conductive ferrule; and wherein the temperature sensor is disposed on the ferrule.

Preferably, a series of regularly spaced markings are provided on the exterior surface of the coaxial cable along its length. Preferably, the markings comprise alternately light and dark coloured sections. Preferably, the light and dark coloured sections are each about 1 cm long.

Preferably, the radiation-emitting portion includes a substantially cylindrical portion integral with the tapering portion. Preferably, the elongate conductor comprises a portion of the inner conductor of a coaxial cable protruding axially beyond the outer casing of said cable.

An advantage of the invention is that the dielectric tip (radiation emitting portion) of the elongate member or probe is designed to emit microwaves; and when the microwave power is applied the probe is withdrawn at a certain rate which, in conjunction with the chosen power output, gives a certain, essentially predictable, depth of thermal penetration into the surrounding tissue.

A further advantage is that, because the microwaves heat the surrounding tissue directly, there is no need to wait for the heat to penetrate the vein wall.

An additional advantage is that a wide range of treatment rates is possible with the correct combination of power, withdrawal rate and choice of frequency. In addition, treatments of vein defects may have an intensity profile whereby the radiation intensity is suitably varied along the length of the defect.

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 (PRIOR ART) is a general schematic diagram of the radiation delivery system that may be used in accordance with one aspect of the present invention;
Figure 2 shows (a) a cross-sectional view, (b) an exploded view, and (c) a plot of the resulting radiation field pattern, for a first embodiment of a radiation applicator or probe that may be employed according to one aspect of the invention;
Figure 3 shows a cross-sectional view of a second embodiment of the probe;
Figure 4 shows (a) a cross-sectional view, (b) an exploded view, and (c) a plot of the resulting radiation field pattern, for of a third embodiment of the probe;
Figure 5 shows a cross-sectional view of a fourth embodiment of the probe;
Figure 6 illustrates (a) an overall view, (b) a close-up view, and (c) a schematic view in use, for an embodiment of the cable employed in the implementation of one aspect of the present invention;
Figures 7(a) to 7(d) depict schematically the movement of the probe in the treatment, according to one aspect of the invention, of a varicose vein;
Figure 8 illustrates one embodiment of the probe, indicating the position of the temperature sensor;
Figure 9 illustrates by flow chart the operation of the software employed on the user's control computer in implementing the invention; and
Figure 10 shows arrangement(s) for handling the withdrawal of the cable and probe in alternative embodiments of the invention.

It will be appreciated by persons skilled in the art that the electronic systems employed, in accordance with the present invention, to generate, deliver and control the application of radiation to parts of the human body, and the applicator construction, may be as described in the art heretofore. In particular such systems as are described in commonly owned published international patent applications WO95/04385, WO99/58642 and WO00/49957 may be employed (except with the modifications described hereinafter): full details of these systems have been omitted from the following for the sake of brevity.

Turning to Fig. 1, this is a general schematic diagram of the radiation delivery system that may be used to implement the present invention. The probe 1 is supplied with a microwave frequency input in the microwave spectrum, preferably in the region of 1-12 GHz, from a microwave frequency generator source and amplifier 14. The amplified signal is passed to the probe 1 via the waveguide line 15 and the coaxial feed line 12. Although the provision of stubs (not shown) may permit tuning of the probe to the specific load, fine tuning is provided by the tuning network 16: this controls the fine tuning of the match of power into the loaded probe. A tuning network may advantageously be used in the invention to ensure that the minimum amount of power is reflected throughout the treatment. An arbitrary level of, for example, less than 10% reflected power from the radiating portion of the elongate member is taken as acceptable.

However, in preferred embodiments of the invention, careful choice of the dimensions and properties of the dielectric, and of the length of the central conductor, of the probe 1 means that probe 1 is optimised to match the tissue to be treated, obviating the need for tuning network 16. The power level

of the source/amplification unit 14 is monitored by a power sensor on the waveguide line 15. A thermometry unit is provided to take the temperature sensor readings at the probe/tissue interface. The various signals are collated and conditioned and fed into a PC/user interface 19 which may interface with a user's conventional PC graphics monitor 20. In this way, the user may vary the frequency of the source 14, set the power level required, and vary the tuning network 16 to achieve optimum match into a load. Also during treatment, real-time graphs of temperature data can be viewed on the monitor 20.

The methodology of treating hollow anatomical structures, such as varicose veins, will be discussed in detail later in this disclosure. First, the configuration of various radiation applicators or probes (hereafter "probe") that may be employed in such treatments will be described.

Figure 2 shows views of a first embodiment of a probe that may be employed according to one aspect of the invention. In Fig. 2(a) there is shown the probe generally designated 1 that comprises the end portion 202 of the coaxial cable 204 supplying microwave radiation from the previously described source, a ferrule 206 around the end portion 202, a dielectric member 208, a conductor 210 within the dielectric member 208 and formed by a protruding section of the internal conductor of the coaxial cable 204, and, in this embodiment, a tip member 212. Optionally, the probe 1 may include an outer protective sheath 214, for example made of fluorinated ethylene propylene (FEP). In use, the microwave radiation supplied via cable 204 is emitted by the dielectric member 208 into adjacent tissue: the dielectric member thus forms a monopolar radiating tip designed to radiate at the chosen frequency.

Probes of 3.4mm and 4.8mm diameter have been constructed; however, other diameters are possible depending on the size of the hollow anatomical structures, but will typically be less than 1.2cm. The diameters and lengths of the dielectric member 208 depend on the chosen dielectric properties, the length of the central conductor 210, the frequency of operation and the required diameter of the probe 1. The exact dimensions are chosen so as to minimise reflection when the probe is in tissue.

The power radiated at the tip of the probe 1 by the dielectric member is typically about 1.3 Watts per mm of circumference. With regard to the dimensions mentioned in the aforementioned drawings, the circumference is equal to $\pi(f+2e)$. Larger applicators may need slightly more power to radiate the same depth of thermal penetration; for example, a 3.4 mm dia. probe can radiate 15.1 W total output (1.4 W/mm of circumference), and a 4.8 mm dia. probe can radiate 20 W total output (1.3 W/mm of circumference). Larger applicators radiate more total power, but slightly less power per mm of circumference to achieve the same depth of thermal penetration.

A temperature sensor (not shown), in the form of a thermocouple linked to the aforementioned control system, is preferably provided on the probe: this is suitably disposed on the ferrule 206 and insulated therefrom, for example by plastic tape. (Alternatively, the temperature sensor may be a fibre optic

device. In this case, since the fibre optic is not directly heated by the microwave field, it could also be placed on the dielectric member.)

In this embodiment, the dielectric member 208 includes a dielectric generally cylindrical portion 214 and a dielectric generally conical tapering portion 216.

The dimensions may be defined as follows.

a = thickness of coaxial cable 204 (including sheath)

b = thickness of coaxial cable 204 (without sheath)

c = overall length of the ferrule 206

d =length of non-tapered, cylindrical portion 215 of dielectric member 208

e = thickness of sheath 214

f = diameter of ferrule 206 and dielectric member 208 (not including sheath 214)

g = diameter of metal tip member 212

h = length of metal tip member 212

i = total length of dielectric member 208

j = length of non-tapered part of ferrule 206

k = length of central conductor 210 that extends beyond the insulated part of the coaxial cable 204.

Figure 2(b) is an exploded perspective view of the probe 1, showing its main constituent parts.

The outer conductor (not shown) of the coaxial cable 204 may be electrically connected to the ferrule 206, which is made of a conductive material such as aluminium. The cable 204 may feed microwave radiation to the probe 1 at various frequencies, and preferably 9.2 GHz in this embodiment. The dielectric member 208 may be made of a known dielectric material, such as Hik 500f, available from Emerson & Cummings, or a hard ceramic dielectric material, such as zirconia (TECHNOX®) which has a permittivity K=25. However, in this embodiment the material is a dielectric material (polyaryletheretherketone (PEEK™)) with permittivity K=3.4. The tip member 212 is made of copper and fixedly attached with, and in good electrical contact with, the end of the conductor 210, for example by soldering or by gluing with an electrically conductive adhesive.

The dimensions (in mm) of the probe 1 in this embodiment are as follows.

a	b	c	d	e	f	g	h	i	j	k
3.1	2.7	5	5	0.2	4.4	2	1.1	11.6	3	12.7

Figure 2(c) is a view of the radiation field pattern generated by the probe of Fig. 2(a) in use. Lighter areas indicate greater intensity: it can be seen that in this embodiment the maximum intensity (white area) is located near the very tip of the probe 1. This embodiment is intended to achieve instant occlusion of the hollow anatomical structure.

Figure 3 shows a second embodiment of the probe 1': the construction is the same as the first embodiment, except as described below.

In this embodiment, the cylindrical portion of the dielectric member 208' is omitted, and the latter includes only the tapering portion 216'. In this embodiment, the material is a dielectric material (Hik 500f or Technox 2000) with permittivity K=25.

The dimensions (in mm) of the probe 1' in this embodiment are as follows.

a	b	c	d	e	f	g	h	i	j	k
2.7	2.3	3.5	n/a	0.2	3	2	1.1	2.9	2	4.0

n/a - not applicable

This embodiment is of a narrower construction and is suited to treatment of narrower anatomical structures.

Figure 4 shows views of a third embodiment of the probe 1": the construction is the same as the first embodiment, except as described below.

Referring to Fig. 4(a), in this embodiment, the conductor 210" does not extend along the entire length of the dielectric member 208": here, it extends about half way, and slightly beyond the axial length of the cylindrical portion 215". Also, the tip member is omitted and the tip of the probe 1" is therefore formed by the end tip 217 of the tapering section 216". In this embodiment, the material is a dielectric material (Hik 500f or Technox 2000) with permittivity K=25.

Figure 4(b) is an exploded perspective view of the probe 1", showing its main constituent parts.

The dimensions (in mm) of the probe 1" in this embodiment are as follows.

a	b	c	d	e	f	g	h	i	j	k
3.1	2.7	5	3	0.2	4.4	n/a	n/a	8.1	3	3.5

n/a – not applicable

Figure 4(c) is a view of the radiation field pattern generated by the probe 1" of Fig. 4(a) in use. Lighter areas indicate greater intensity: it can be seen that in this embodiment the maximum intensity (white area) is located away from the tip of the probe 1"; rather it is concentrated at the base of the dielectric member 208". This embodiment is designed to deliver heat as uniformly as possible. Assuming that sufficient heat has been delivered, occlusion may be achieved at some point post-treatment.

Figure 5 shows a fourth embodiment of the probe 1"': the construction is the same as the third embodiment, except as described below.

In this embodiment, the dielectric member 208"' is of a smaller, thinner construction. In this embodiment, the material is a dielectric material (Hik 500f or Technox 2000) with permittivity K=25. Here, the conductor 210"' does not extend along the entire length of the dielectric member 208"': it extends by an amount about equal to the axial length of the cylindrical portion 215"'.

The dimensions (in mm) of the probe 1 in this embodiment are as follows.

a	b	c	d	e	f	g	h	i	j	k
2.7	2.3	3.5	4.1	0.2	3	n/a	n/a	7.1	2	4.1

n/a – not applicable

This embodiment is of a narrower construction and is suited to treatment of narrower anatomical structures.

As used herein, references to the probe 1 are, as appropriate, references to the probe 1, 1', 1", and/or 1"'. Similarly, references to the dielectric member 208 are, as appropriate, references to the dielectric member 208, 208', 208", and/or 208"'; and so on.

In all the embodiments described above, the length of the central conductor 210 is selected to optimise the transfer of energy, i.e. to minimise reflection of radiation when the probe 1 is in tissue. The length of the centre conductor is an integer number of quarter wavelengths long, this wavelength being determined by frequency of the radiation and the permittivities of the materials surrounding the centre conductor within the microwave field. Calculating the length of a particular integer number of quarter wavelengths in the dielectric therefore gives an approximate appropriate length. This is then altered and optimised by testing (either on computer or by building prototypes) to take account of the complex interactions of the waves in order to achieve minimum reflected power.

Similarly, in all embodiments, the probe 1 is shaped and dimensioned for ease of use: its rounded form enables the probe 1 to be readily inserted into a vein and also allow the vein to shrink easily back to its original size (diameter) following withdrawal.

Figure 6 illustrates the coaxial cable 204 employed in the implementation of one aspect of the present invention. More specifically, Fig. 6(a) is a view of the entire cable 204 having the probe 1 fixed to one end thereof, the cable 204 having visible markings thereon.

Referring to Fig. 6(b), this is a close up view of part of the cable 204. In this embodiment, equal length, alternating light sections 602 and dark sections 604 comprise the markings provided on the surface of the cable 204. The markings may be formed during fabrication of the outer casing of the cable 204 itself, or they may be formed by the application of light tape or paint to a dark coloured cable 204, or vice versa, post-manufacture. For example, the markings may be black and white, or black and yellow. Suitably, the markings are about 1 cm wide. The markings provide advantages in use, as further described hereinafter. In other embodiments, the markings may be of unequal length, or they may have a length that varies in a predetermined fashion along the length of the cable 204.

As shown in Fig. 6(c), the probe 1 (not shown) on the end of cable 204 has been inserted into a hollow anatomical structure (e.g. a vein; not shown) inside a body part (e.g. a leg) 606 via a very small incision 608. During treatment, as described in detail below, the cable 204 is pulled by the user (medical professional, practitioner, technician, nurse, etc.) in the direction of arrow A, thereby gradually revealing the markings 602, 604 on the cable 204.

Figure 7 depicts schematically the movement of the probe in the treatment, according to one aspect of the invention, of a varicose vein 702. The diagram is not in proportion: the dimensions and relative

size of the vein 702 and probe 1 have been altered merely for the sake of clarity and ease of illustration. The vein 702 will have already been identified and diagnosed as having a section 704 of varicose tissue. Obtaining uniform heating along the length of the vein 702 with a fixed power output is achieved by controlled withdrawal of the probe 1. The rate of withdrawal is correlated to the depth of thermal penetration.

The preferred methodology is as follows.

The maximum size of the vein to be treated (e.g. the greater saphenous vein – GSV) is determined by ultrasound scanning prior to the procedure. A probe with an outer diameter as close as possible to this maximum size is then chosen. Preferably, a probe 1 is selected with an outer diameter at least as large as the inner diameter of the section of vein to be treated; and this ensures that, during operation, the probe 1 will be tight against, and even expand, the inner wall of the vein, so that the minimum amount of blood is subjected to radiation. This has two further effects: (i) to maximise the microwave energy deposited in the vein wall; and (ii) to evenly treat the whole circumference of the vein wall (as the probe and vein wall are thus concentric). In an alternative procedure, also to minimise the amount of irradiated blood, a measure may be taken to stem the flow of blood through the vein (e.g. "Pringle manoeuvre") so that minimal amounts of blood are subjected to the radiation treatment.

An incision is then made in order to insert the probe at the end of the length of vein 702 to be treated. The probe may be inserted percutaneously, through a catheter, or directly introduced following exteriorisation of the vein 702, as is known in the art. In the case of the GSV, this is likely to be either at the ankle, at the knee, or both.

The probe 1, once it has been introduced into the vein 702 by suitable incision (not shown), is threaded up, or down, i.e. by the user pushing the cable 204 in the direction of arrow B, as shown in Fig. 7(a), to where the treatment is to start. The movement continues, indicated in Fig. 7(b), so that the probe 1 is moved past the varicose section 704 of the vein 702. In the case of the GSV, this means threading the probe up to the saphenofemoral junction.

As illustrated in Fig. 7(c), the emitting part (dielectric member 208) is paused at or just beyond the end of the varicose section 704, the relative positions being determined by suitable means, such as ultrasound scanning. Next, the microwave delivery system (see Fig. 1) is activated. This system is preferably configured, by suitable programming or software tool, so that audible tones (or "beeps") are emitted so as to be easily and distinctly heard by the user. The tones are emitted at a regular rate; however, means may be provided, using techniques well known in the art, for varying the frequency of the beeps between procedures or between patients (i.e. different treatment intensities for different treatments of the same patient at different times (occasions), or different treatment intensities for different patients at different times). Alternatively, the tones may be generated by a conventional tone-generating device separate from the main system.

In another embodiment, the "beeps" may be emitted at a non-regular rate, with the markings on the cable 204 being a uniform pattern with equal length markings, thereby generating a pattern of radiation intensity that varies along the length of the vein section treated.

In another embodiment, the "beeps" may be emitted at a regular rate, with the markings on the cable 204 being a non-uniform pattern with unequal length markings, thereby generating a pattern of radiation intensity that varies along the length of the vein section treated.

In another embodiment, the "beeps" may be emitted at a non-regular rate, with the markings on the cable 204 being a non-uniform pattern with unequal length markings, the pattern of radiation intensity along the length of the vein section accordingly having a different pattern to achieve the desired and designed variable penetration.

It should be noted that evenly irradiating the vein wall is not necessarily the same as evenly heating the vein wall. The probe tip starts at body temperature. When power is first applied some heat is lost to the probe as it heats up. More energy per unit length of vein is therefore required to obtain the same depth of thermal penetration. The withdrawal rate therefore needs to be slower to start with and speed up as the applicator warms up.

The radiation is switched on via the system's user interface, as indicated in Fig. 7(c); this, in turn and via the software causes the emission of "beeps" to commence (the operation of the software is discussed in further detail hereinbelow). Thereupon the user, grasping the cable 204, withdraws the probe 1 by pulling the cable 204 in the direction of arrow C. In doing so, the user ensures that he pulls at such a rate that the markings 602, 604 become visible (Fig. 6(c)) in succession, one (e.g. black or white) marking in time with each successive tone or "beep". In this way, the radiation emitting dielectric member 208 on the probe 1 passes along the varicose section 704 at a uniform or near-uniform rate while emitting the controlled dose of radiation. When the user achieves this, the thermal penetration of the probe in homogeneous tissue can be effectively guaranteed: this will typically be to a depth of about 1.5mm. This provides for effective treatment of the varicose section via microwave-induced thermal ablation, causing therapeutic occlusion of the tissue.

As the probe comes to the end of the length to be treated, a red band appears on the shaft to warn the user that the probe is about to appear. At the end of this red band the user turns off the power and thus stops the treatment.

The treatment may, in some cases, be performed in conjunction with ligation.

Referring to Fig. 8, during all operation, the temperature of the tissue is constantly sensed by the thermocouple 802 on the probe 1 and the temperature monitored. Although the withdrawal rate is determined by the audible tones, the system is still required to ensure that the user withdraws while ensuring patients safety. The thermocouple 802 is kept relatively cool due to it constantly being

brought into contact with unheated tissue. It is typically 1-2mm back from the ferrule-dielectric interface 804. In the illustrated embodiment (corresponding to the probe design of Fig. 4(a)), the thermocouple 802 is 1.5 mm back from the ferrule-dielectric interface 804. However, this distance may be set at different values, depending on the embodiment of the probe 1. The thermocouple 802 is mounted on the exterior surface 806 of the ferrule 206, suitably by gluing, taping or any other suitable fixing technique. The thermocouple 802 is insulated from the metallic ferrule 206, for example by means of insulating tape. The reading from the thermocouple is carried away via line 808 to the control system (computer) of Fig. 1. As mentioned with respect to Fig. 2, the thermocouple 802 is covered by the protective sheath 214 when the latter is provided over the probe 1.

In the event of the user failing to withdraw, or not withdrawing quickly enough, thermal conduction carries heat forward to the thermocouple. This is used as a safety parameter that can be used to switch the microwave power off. The temperature measured by the thermocouple is typically 60°C. Preferably, the system is configured (e.g. programmed) to cut out the microwave power if the measured temperature reaches 70°C.

Figure 9 illustrates by flow chart the operation of the software employed on the user's control computer in implementing the invention. As indicated in Fig. 9(a), a check for switch on of mains power to the microwave delivery system is constantly made until it is determined (s2) that this has occurred (TRUE), whereupon processing moves to the next stage.

Further processing commences at ② in Fig. 9(b). Here, a check is made at s4 to see if microwave power to the probe 1 is ON. If it is not ON (i.e. FALSE), either the sounding of audible tone is ceased (at s6) or the sounding is not initiated.

If it is determined at s4 that microwave power to the probe 1 is ON (TRUE), then the sounding of audible tones at predetermined intervals as hereinbefore described is initiated (s8). Next, the current temperature sensed by the thermocouple is recorded. At this stage, a comparison is made (s12) to see if the current thermocouple temperature exceeds a preset threshold temperature. If FALSE (threshold not exceeded), the processing returns to step s4.

If the test is TRUE (temperature exceeds threshold), the microwave power is instantaneously cut at s14, and alarm signal is sounded (different from the series of audible tones) and/or an alert message displayed (s16). Thereafter, processing continues to s6, where the series of audible tones is ceased, and the procedure terminates.

Turning to Fig. 10, this shows arrangement(s) for handling the withdrawal of the cable 204 and probe 1 in alternative embodiments of the invention. The markings combined with the tones provide a simple way to control the withdrawal rate. However, in the embodiments of Fig. 10, computer 1002 is the control computer of Fig. 1, and the cable 204 is withdrawn via a withdrawal rate sensor 1004 linked to

computer 1002. Optionally, a drum 1006, for receiving the wound up cable 204, is provided, and this may be via a mechanical actuator 1008 that is also linked to computer 1002.

The operation of various embodiments is as follows.

Various purely mechanical systems may be implemented. In one example, the cable 204 is reeled back onto the drum 1006 whose speed of rotation is predetermined (e.g. driven by a variable speed motor (not shown). In another example, the cable 204 is pulled back through rollers (not shown) whose speed is predetermined (in a similar manner to the driven rollers in sheet feeding apparatus, such as printing and copying machines). Alternatively, the cable 204 is pulled back through the rollers and then reeled onto the drum 1006.

In an embodiment employing manual withdrawal of the cable 204 with feedback guidance, the speed of withdrawal of the cable 204 is sensed through rollers placed on the cable 204, or through which the cable passes, by the drum 1006 reeling the cable 204 in, or by an optical sensor (not shown) detecting the movement of the cable 204 itself.

In an embodiment employing mechanical techniques with sensor feedback, the mechanical withdrawal is monitored by the withdrawal rate sensor 1004, e.g. an optical sensor, in order to detect the movement of the cable 204 and ensure that the correct withdrawal rate is being achieved. The mechanical actuator and drum may or may not be used.

In each of the above cases, the withdrawal rate sensor 1004 may be linked to a treatment screen (Fig. 1) attached to computer 1002, which tells the user to speed up or slow down. The latter indications may alternatively or additionally be given audibly via the speaker (not shown) of the computer 1002, or other audio equipment attached to, and controlled by, the computer 1002. In certain cases, the user can thus adjust the rate of manual withdrawal, or the speed of the drum 1006 or the mechanical actuator 1008 until an indication (screen message and/or tone) is achieved indicating that the withdrawal rate is in conformity with the desired treatment.

Claims:

1. A method of treating hollow anatomical structures, for example varicose veins, comprising:

providing an elongate member, the elongate member including an emitter, the emitter being coupled to a source of microwave radiation and being adapted to emit said radiation;

introducing the elongate member into a hollow anatomical structure, the hollow anatomical structure including a section of target tissue;

traversing the elongate member past the section of target tissue at a controlled rate while said emitter emits microwave radiation of a predetermined intensity into said section.

2. The method of claim 1, wherein the hollow anatomical structure is a vein, and said section of target tissue comprises a section of varicose tissue.

3. The method of claim 1 or 2, wherein the traversing is performed at a predetermined rate, for example at a predetermined constant rate.

4. The method of claim 3, wherein said predetermined constant rate is about 2.5mm per second.

5. The method of any of claims 1 to 4, wherein the elongate member is mounted on the end of a flexible elongate meter said elongate meter having a series of regularly spaced markings along its length; and

said traversing is performed while a series of equally time-spaced audible tones is emitted; and

and said traversing is performed by a user at a rate such that each of said markings become visible to the user in time with a respective one of said audible tones.

6. The method of claim 5, wherein the markings are non-regularly spaced instead of regularly spaced.

7. The method of claim 5 or 6, wherein the audible tones are non-equally time spaced instead of equally time-spaced.

8. The method of claim 5, 6 or 7, wherein said traversing step is performed by withdrawing the elongate member from the vein by the user pulling on the elongate meter, thereby exposing said markings.

9. The method of claim 5, 6 or 7, further comprising:

providing a motion sensor, for example an optical sensor, positioned to sense the motion of the meter, and

providing a controller, for example a computer, coupled to the motion sensor,

wherein said traversing step is performed by withdrawing the elongate member from the vein by pulling on the elongate meter, wherein during said pulling step the controller issues audible and/or visible indications to the user, and wherein said audible and/or visible indications indicate that the speed of withdrawal of the elongate member is too slow, or is too fast, or is correct.

10. The method of claim 9, further comprising:

providing a mechanical actuator, the mechanical actuator being coupled to the controller and adapted to impart translational motion to the elongate meter,

wherein said pulling is provided by driving the mechanical actuator, under the control of the controller and/or the user, to impart said translational motion and thereby withdraw said elongate member.

11. The method of claim 9 or 10, further comprising:

providing a drum;

wherein said step of pulling on the elongate meter includes winding the elongate meter onto said drum.

12. The method of any of the preceding claims, wherein the traversing step is preceded by the step of moving the elongate member in a first direction along the vein until the emitter has passed beyond said section of target tissue, and the traversing step is performed by the user withdrawing the elongate member in a second direction, opposite to said first direction.

13. The method of any claims 5 to 12, wherein the markings comprise alternately light and dark coloured sections.

14. The method of claim 13, wherein the light and dark coloured sections are each about 1 cm long.

15. The method of any claims 5 to 14, wherein the elongate member is coupled to the source of radiation via a coaxial cable, and the markings are provided on the exterior surface of the coaxial cable.

16. The method of any of the preceding claims, wherein said predetermined intensity of microwave radiation is about 1.3 to 1.4 W per mm of circumference of the elongate member, whereby said emission of radiation achieves occlusion of said section of target tissue during said traversing step.

17. The method of any of the preceding claims, wherein a temperature sensor is provided on said elongate member, and the method further includes monitoring a temperature provided by the sensor and indicative of the temperature of the section of varicose tissue during said traversing step.

18. The method of claim 17, further including stopping the emission of said microwave radiation if the temperature sensed by said sensor is at or above a predetermined level.

19. A method of treating hollow anatomical structures substantially as hereinbefore described with reference to the accompanying drawings.

20. An applicator for applying radiation to hollow anatomical structures, for example varicose veins, comprising:

an elongate member, the elongate member including an emitter, the emitter being coupled to a source of microwave radiation and being adapted to emit said radiation;

wherein the emitter includes

a radiation emitting portion made of dielectric material and having an axis of elongation, and

an elongate conductor within and extending at least partially along the radiation emitting portion,

the radiation emitting portion being shaped and dimensioned so as to emit said radiation at a predetermined intensity in a field of limited dimensions adjacent thereto, whereby occlusion of the tissue of a hollow anatomical structure within said field is effectively accomplished.

21. The applicator of claim 20, wherein the radiation emitting portion includes a generally conical tapering portion, the tapering portion thereby forming a tip for insertion into a hollow anatomical structure.

22. The applicator of claim 21, wherein the elongate conductor extends along the entire length of the radiation emitting portion, whereby said field is disposed, in use, substantially around said tip.

23. The applicator of claim 21, wherein the elongate conductor extends partially along the length of the radiation emitting portion, whereby said field is disposed, in use, substantially around the midsection of said radiation emitting portion and spaced apart from said tip.

24. The applicator of any of claims 20 to 23, wherein a temperature sensor is provided on said elongate member, said temperature sensor preferably comprising a thermocouple or a fibre optic sensor.

25. The applicator of any of claims 20 to 24, wherein the elongate member is coupled to the source of radiation via a coaxial cable, and a portion of said cable in abutment with the radiation emitting portion is surrounded by, and attached thereto, by a conductive ferrule; and

wherein the temperature sensor is disposed on the ferrule.

26. The applicator of claim 25, wherein a series of regularly spaced markings are provided on the exterior surface of the coaxial cable along its length.

27. The applicator of claim 25, wherein the markings are non-regularly spaced instead of regularly spaced.

28. The applicator of claim 26 or 27, wherein the markings comprise alternately light and dark coloured sections

29. The applicator of claim 28, wherein the light and dark coloured sections are each about 1 cm long.

30. The applicator of any of claims 21 to 29, wherein radiation emitting portion includes a substantially cylindrical portion integral with the tapering portion.

31. The applicator of any of claims 25 to 30, wherein said elongate conductor comprising a portion of the inner conductor of a coaxial cable protruding axially beyond the outer casing of said cable.

32. An applicator for applying radiation to hollow anatomical structures, substantially as hereinbefore described with reference to the accompanying drawings.

Abstract

Treatment of hollow anatomical structures

A method of treating hollow anatomical structures, for example varicose veins. The method comprises: providing an elongate radiation applicator, the elongate applicator including an emitter, the emitter being coupled to a source of microwave radiation and being adapted to emit said radiation; introducing the applicator into a hollow anatomical structure, the hollow anatomical structure including a section of target tissue; traversing the applicator past the section of target tissue while said emitter emits microwave radiation of a predetermined intensity into said section. Techniques are used (markings on the coaxial cable in conjunction with an audible tone) so that the user makes the traversal at a predetermined rate so that uniform application of the radiation to the tissue, and effective occlusion, occurs. An applicator for performing the treatment is also disclosed, comprising: an elongate member, the elongate member including an emitter, the emitter being coupled to a source of microwave radiation and being adapted to emit said radiation; wherein the emitter includes a radiation emitting portion made of dielectric material and having an axis of elongation, and an elongate conductor within and extending at least partially along the radiation emitting portion, the radiation emitting portion being shaped and dimensioned so as to emit said radiation at a predetermined intensity in a field of limited dimensions adjacent thereto, whereby occlusion of the tissue of a hollow anatomical structure within said field is effectively accomplished.

(Fig. 7)

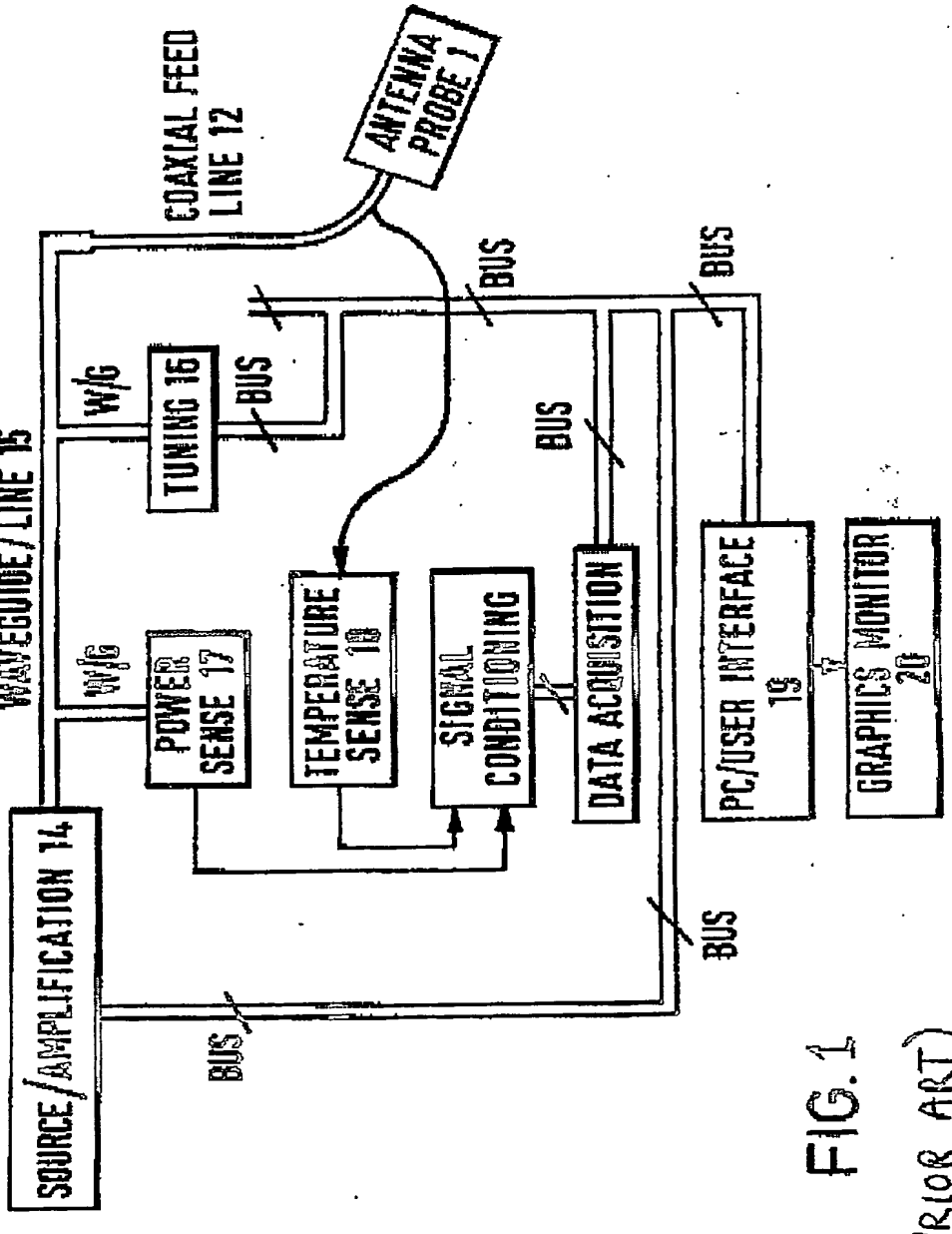

FIG. 1
(PRIOR ART)

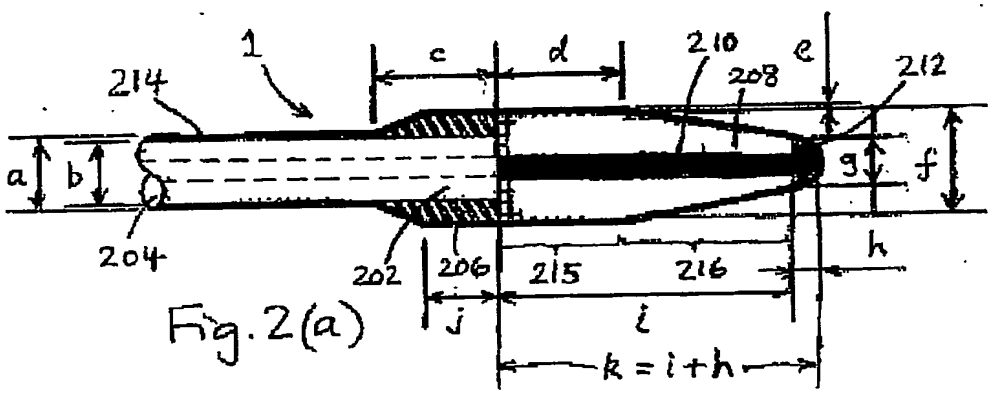

Fig. 2(a)

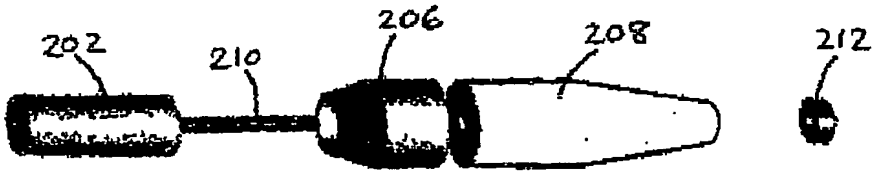

Fig. 2(b)

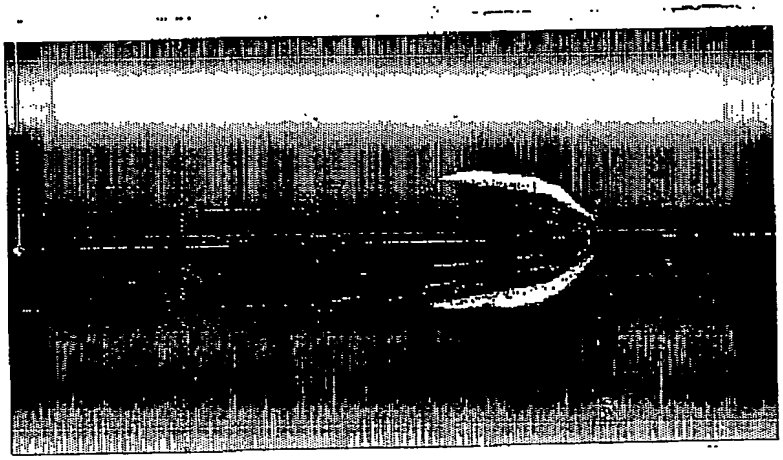

Fig. 2(c)

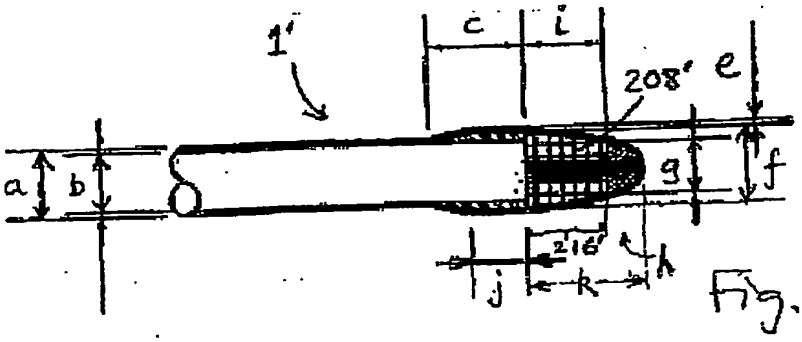

Fig. 3

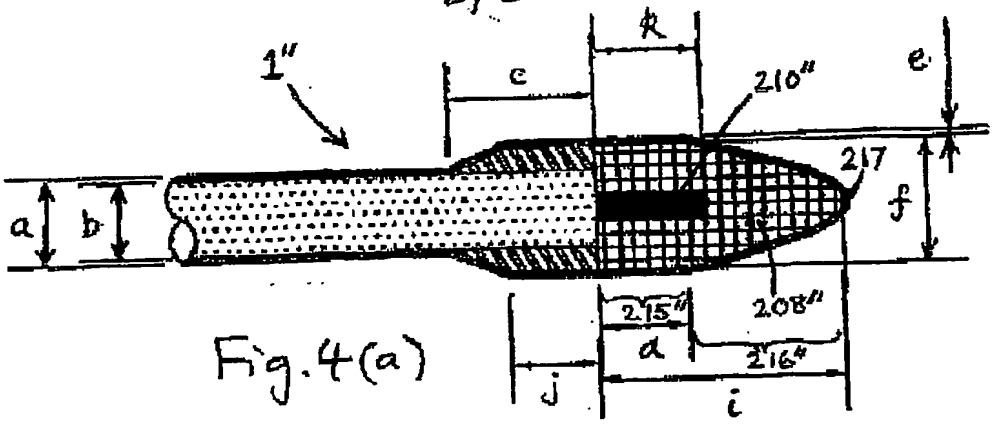

Fig.4(a)

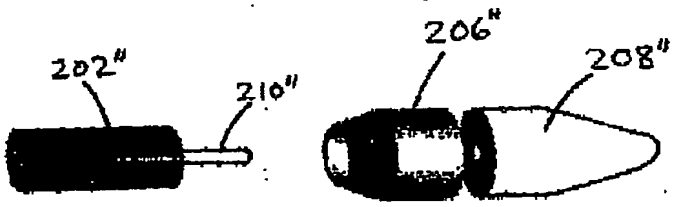

Fig.4(b)

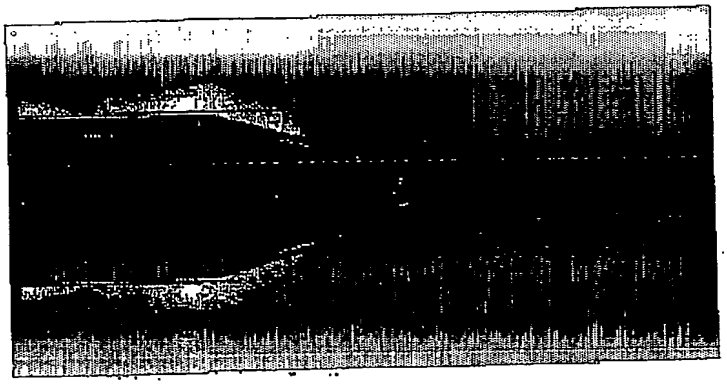

Fig.4(c)

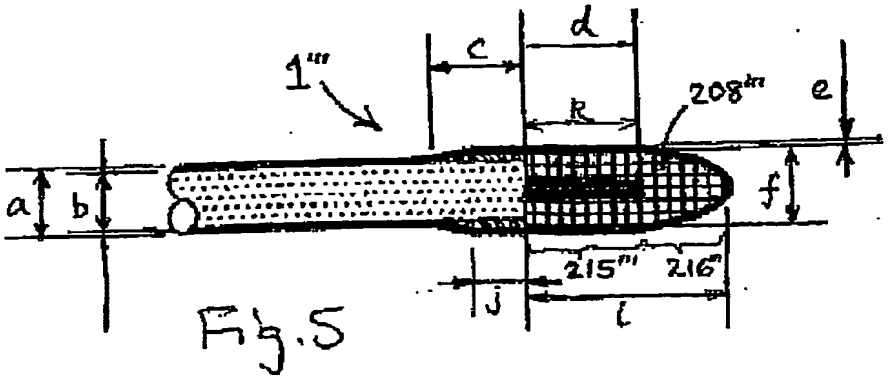

Fig.5

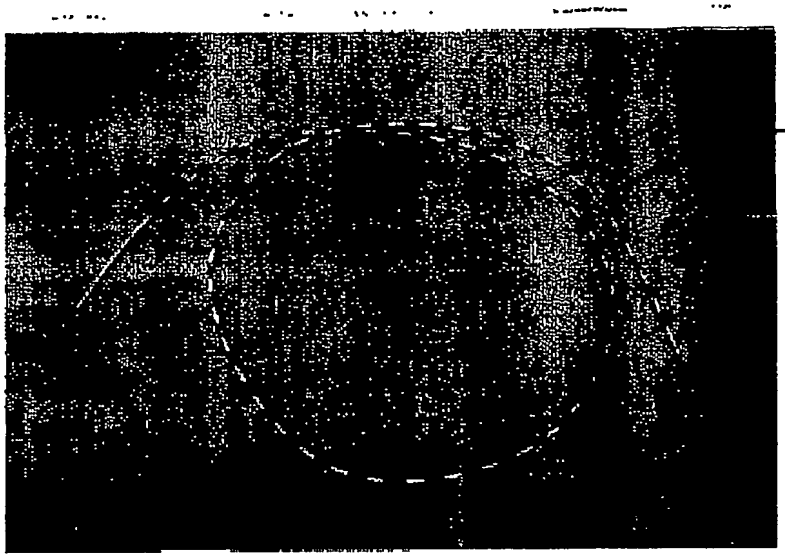

Fig. 6(a)

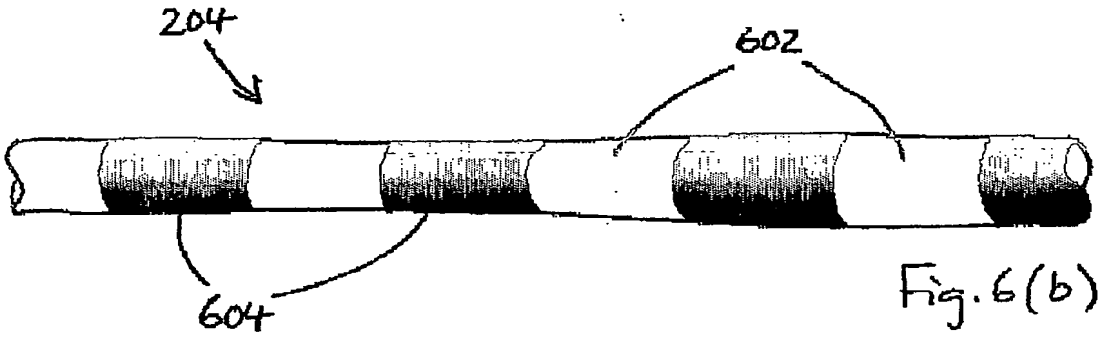

Fig. 6(b)

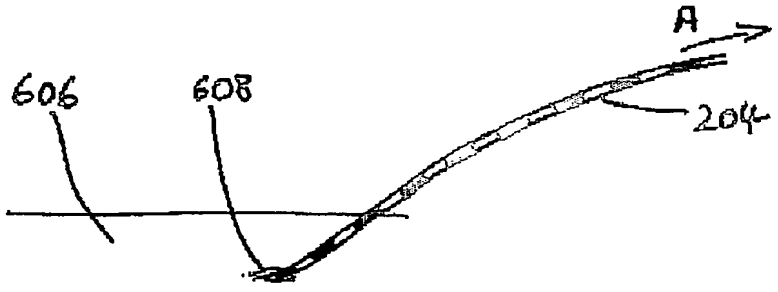

Fig. 6(c)

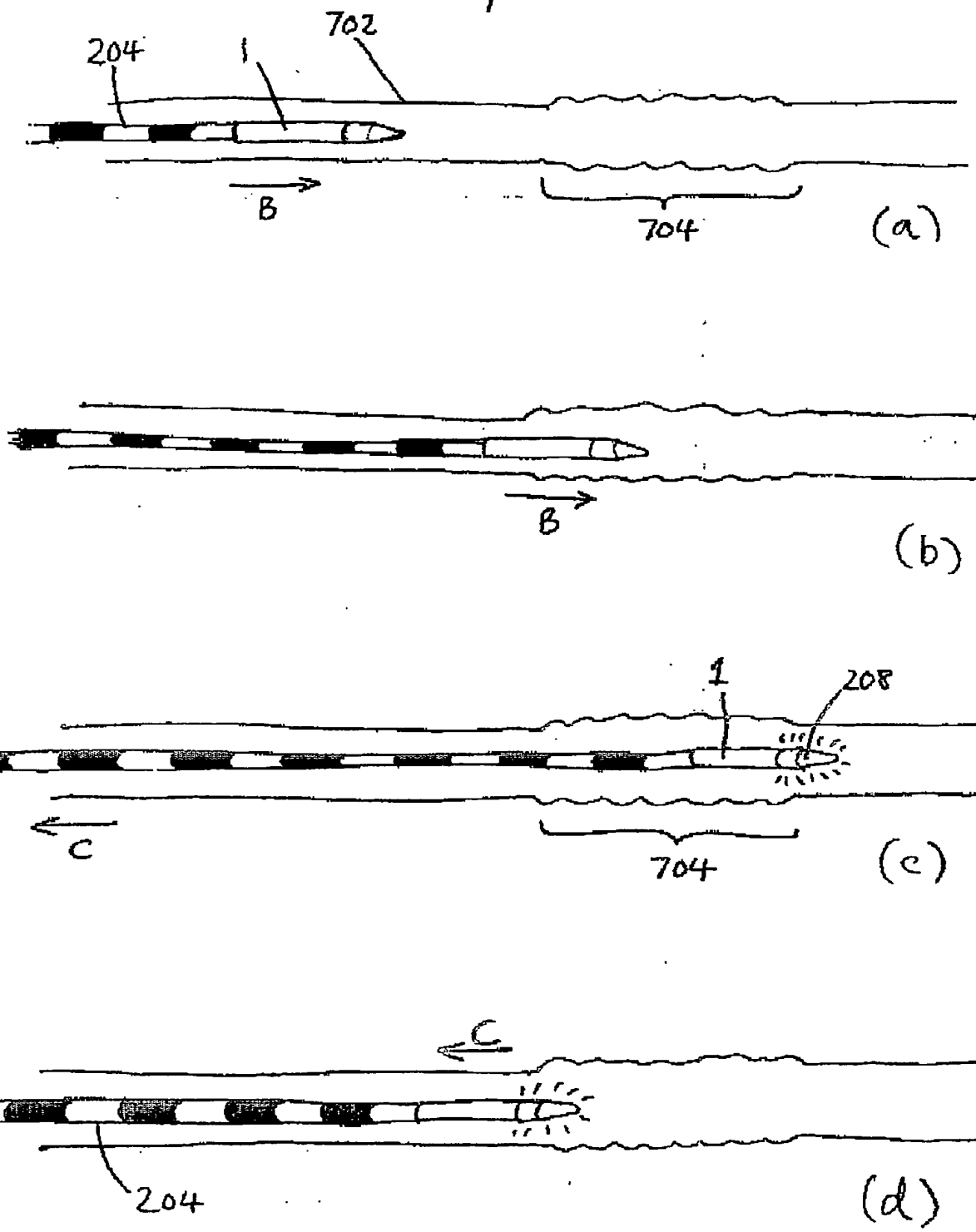

Fig. 7

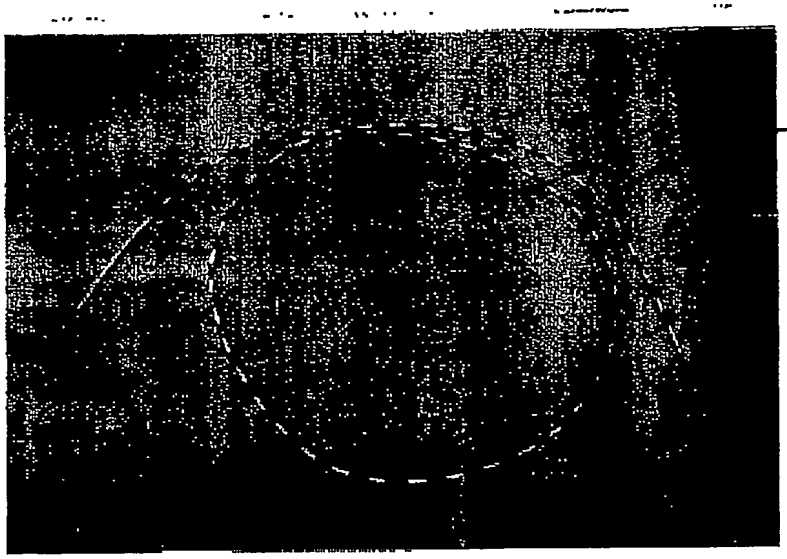

Fig. 6(a)

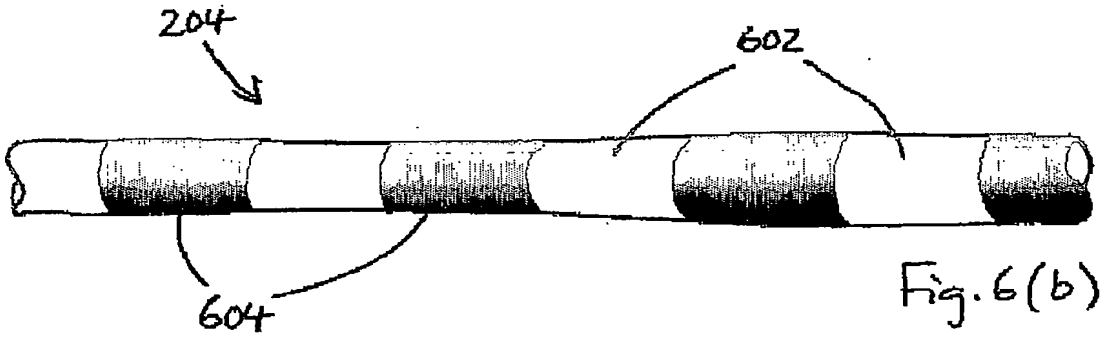

Fig. 6(b)

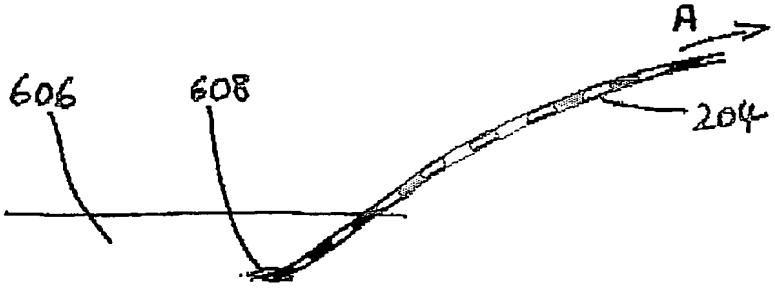

Fig. 6(c)

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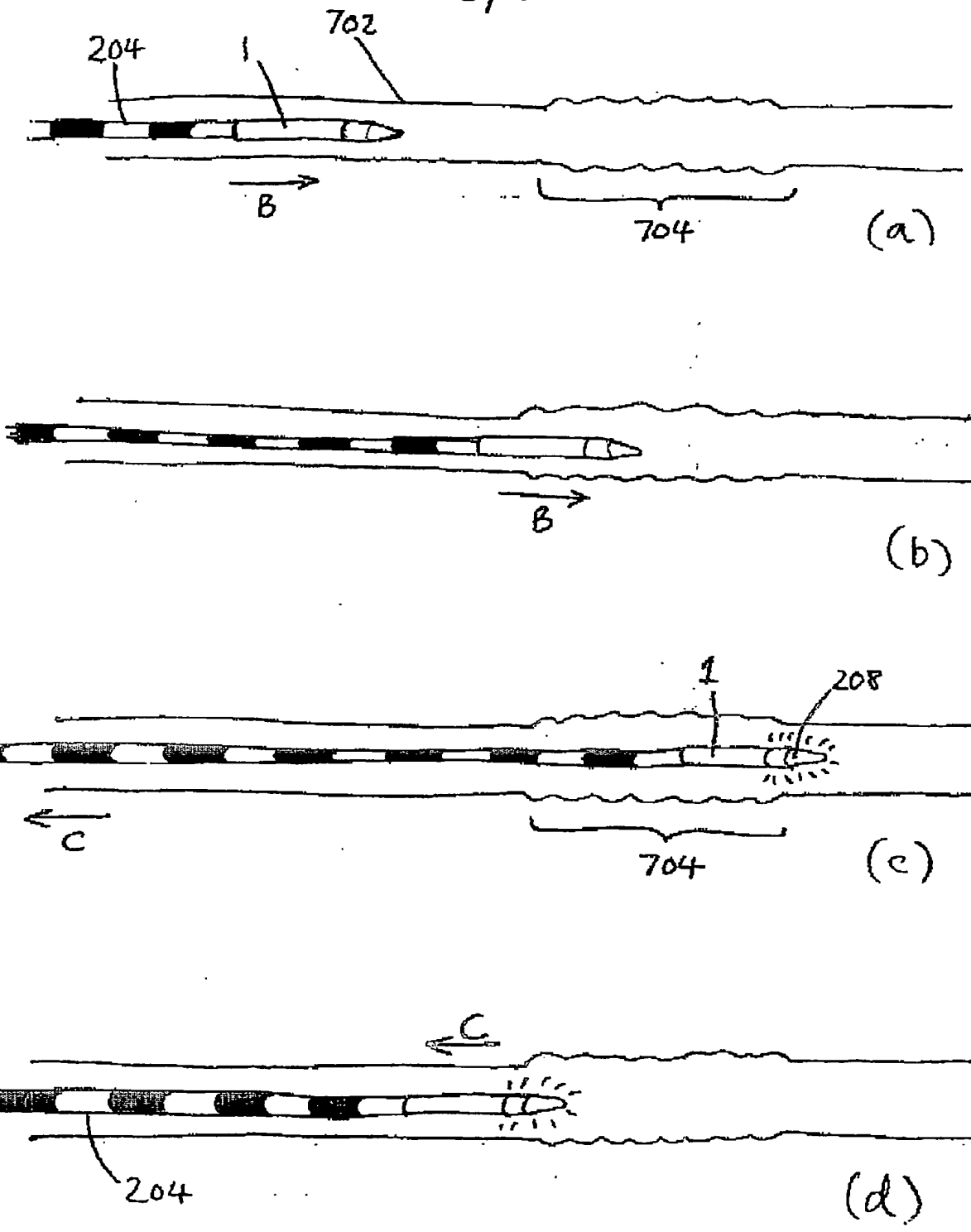


Fig. 7

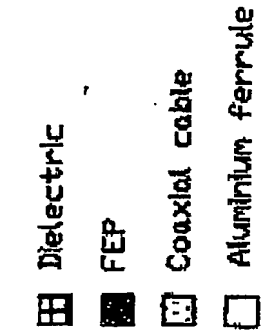
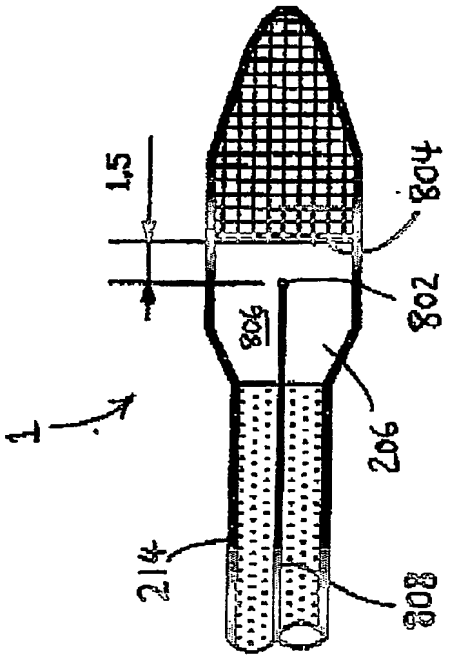


Fig. 8



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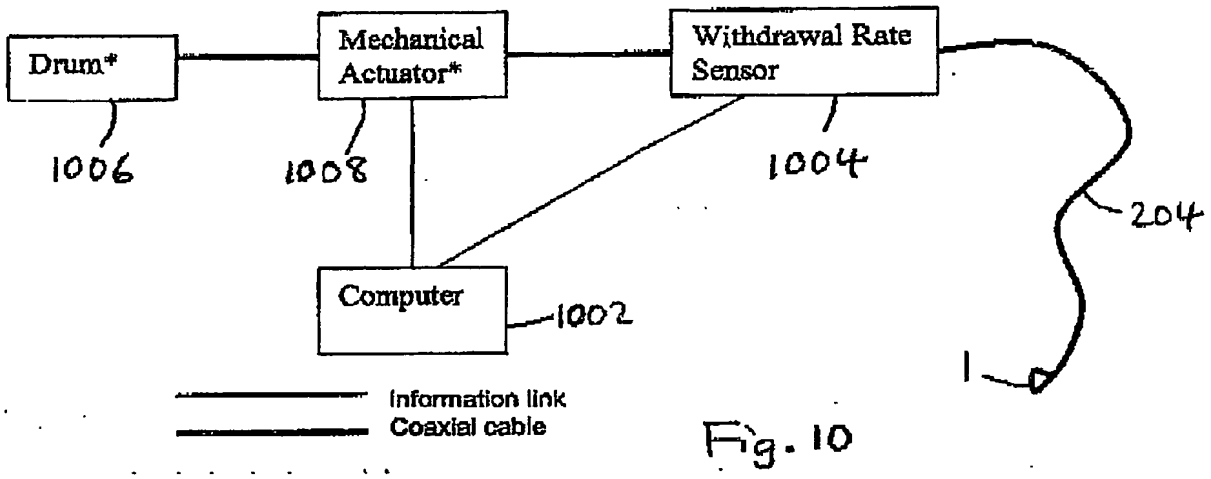

Fig. 10

Monitor Mains Power

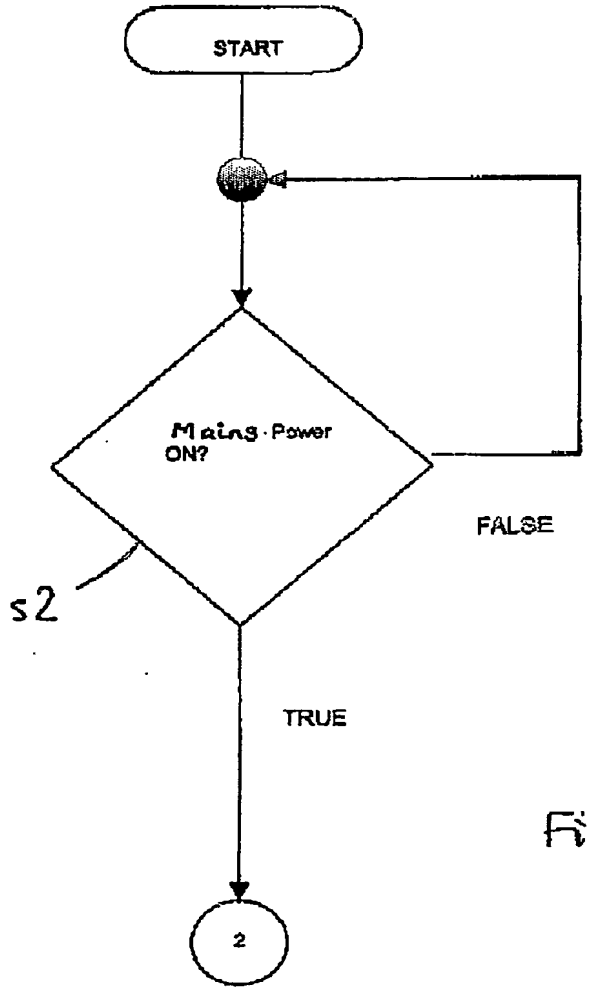

Fig. 9 (a)

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Monitor Treatment

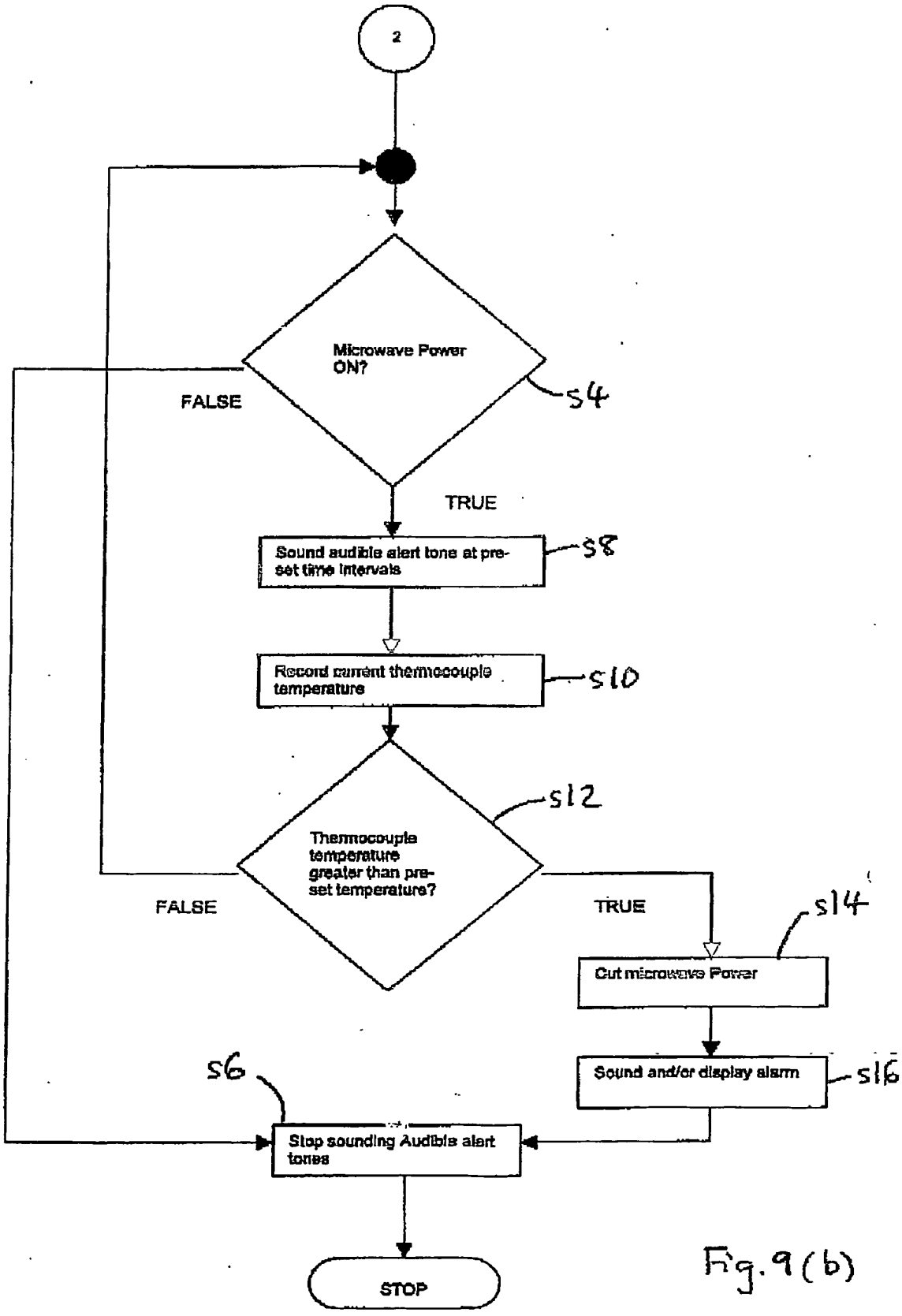

Fig. 9(b)